

## **ATTACHMENT B**

### **REMARKS**

By this amendment, a new set of claims is provided to emphasize the differences between the present invention, which is directed to the use of a cleansing, moisturizing or conditioning composition for skin or hair, and the prior art, which is directed to a cosmetic anti-wrinkle composition which does not cleanse, moisturize or condition, but instead acts to dry out the skin. In light of the amendments to the claims and the arguments as set forth below, Applicant submits that the present application overcomes all prior rejections and has now been placed in condition for allowance.

The present invention, as reflected in the new set of claims, is directed to a hypoallergenic cleansing, moisturizing or conditioning composition for skin or hair which consists essentially of human serum albumin (whether natural or produced recombinantly) and a cleansing, moisturizing or conditioning agent in amounts effective to cleanse, moisturize or condition skin or hair, such as disclosed throughout the Applicant's specification. This composition provides for the first time a cleansing, moisturizing or conditioning composition based on human serum albumin which can be absorbed into the skin to effect and enhance cleansing, moisturization and conditioning of skin and hair in a manner not previously possible. As set forth below, the present compositions differ greatly from the "Exovir" compositions in the prior art which do not cleanse, moisturize or condition (a fact recognized by the inventors in the Exovir references), but instead only provide cosmetic compositions which must be applied after the skin has first been cleansed or moisturized.

In the Official Action, the Examiner rejected previous claims 20 and 14 for various reasons under 35 U.S.C. § 112. Without addressing the specific arguments of the Examiner, this rejection has become moot in light of the new set of amended claims which do not include the language objected to by the Examiner.

In the Official Action, the Examiner rejected the claims under 35 U.S.C. § 102(b) on the basis of Kligman EP 244859 and Miller EP 180968 patent references both issued to Exovir, Inc. These Exovir patents both relate only to cosmetic compositions and not to a cleansing, moisturizing or conditioning composition as set forth in Applicant's claimed invention. This fact is made clear in that in both of the Exovir references, the inventors state that their cosmetic compositions need to be applied **after the skin is cleansed** with a cleansing agent or soap. See EP 180968 at page 5 ("In use as an antiwrinkle agent, before the HSA preparation is applied to the skin, *the skin is cleansed and dried, such as by cleansing with soap and water or by use of a cleansing cream*") and EP 244859 at Example I ("When used as an antiwrinkle preparation, before the lotion is applied to the skin, *the skin is cleansed and dried, such as by cleansing with soap and water or by use of a cleansing cream*") (Emphasis added). Moreover, the Exovir references specifically disclose that their compositions to dry on the skin so that their composition "lifts the skin up and the fine wrinkles therebeneath are smoothed out and removed" See e.g., EP 244859, Abstract. It is thus clear that these compositions are **not** cleansing, moisturizing or conditioning compositions as required by the present claims, and indeed in light of the fact that such compositions dry out the skin so as to "lift the skin up" when dried, these compositions actually **teach away** from the present compositions which

cleanse, moisturize or condition by allowing the active ingredient, i.e., human serum albumin, to be absorbed into the skin or hair.

In the Official Action, the Examiner indicated that the Exovir references anticipated the present invention because they disclosed the use of glycerin in the cosmetic, skin-drying compositions. In fact, the Exovir references do **not** disclose or suggest a composition in accordance with the invention which contains cleansing, moisturizing or conditioning amounts of human serum albumin and a cleansing, moisturizing or conditioning agent. To the contrary, the additional ingredients in the Exovir references, namely sodium silicate and a minor amount of glycerin (about 1%) in EP 244859 and glycerin (about 1 %) in EP 180968 are clearly used for purposes of surface deposition of the active agent, and **not** for purposes of cleansing, moisturizing or conditioning the skin (the references do not disclose or suggest anywhere use on hair). The references go on to teach that a cleansing agent **must** be used prior to the application of the antiwrinkle composition which will dry the skin to be effective (see Examples). Accordingly, it is clear that neither of the Exovir references discloses or suggests the present invention directed to a composition consisting essentially of human serum albumin and a cleansing, moisturizing or conditioning agent in amounts effective to achieve cleansing, moisturizing or conditioning of skin or hair.<sup>1</sup>

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<sup>1</sup> The claim language "consisting essentially of" means that the claim is directed to the specified materials and only those other materials which do not materially affect the basic and novel characteristics of the claimed invention, which in this case is the ability of the composition to provide cleansing, moisturizing and conditioning properties. See MPEP § 2111.03 and PPG Industries v. Guardian Industries, 156 F.3d 1351 (Fed. Cir. 1998).

Applicant thus submits that the prior art Exovir references do not disclose or suggest the presently claimed invention and in fact teach away from the present invention since they clearly fall outside the scope of the present claims calling for a cleansing, moisturizing or conditioning composition. Accordingly, the Examiner's rejections on the basis of the Exovir references are respectfully traversed and should be withdrawn.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

**END REMARKS**